UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,808	10/16/2000	Ib Mendel-Hartvig		2872

7590 08/20/2003

Dinsmore & Shohl
1900 Chemed Center
255 East Fifth Street
Cincinnati, OH 45202

EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	18

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,808	Applicant(s) MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the claims

The amendment filed on June 30, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 42-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is vague and indefinite because the preamble recites "a method for use in a flow matrix but the body of the claim sets forth steps of performing. It is unclear if the claim is a method claim or a use of a method, as recited the claim appears to be a method claim. Step (i) and (ii) set forth steps of performing.

Claim 44 the recitation "mixture of biospecific affinity reactants" is vague and indefinite. It is unclear what "mixture" comprises. Is this a mixture of many different kinds of biospecific affinity reactants or is it a solution of one type of biospecific affinity reagent or does applicant intend something else? See also deficiency found in claim 45 and 46.

Claim 57 is vague and indefinite because it contradicts claim 42. Claim 42 recites "the sample comprising the analyte and an analytically detectable reactant (Reactant*). Claim 57 recites "wherein the Reactant* is predeposited in the matrix upstream of the

DZ. It is unclear how the Reactant* can be in the sample and predepositied in the matrix upstream of the DZ zone at the same time.

Claim 58 is vague and indefinite because it contradicts claim 42. Claim 42 recites "the sample comprising the analyte and an analytically detectable reactant (Reactant*). Claim 58 recites "wherein the Reactant* is predeposited in the matrix upstream of a sample application site". It is unclear how the Reactant* can be in the sample and predeposited in the matrix upstream of a sample application site at the same time.

Claim 60 the recitation "is capable of" is vague and indefinite. The recitation "capable of" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 42-47, 51-53, 56-57, 59-61, 63-68, 72-74, 77-78 and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al (US 5,989,921) in view of Batz et al (US 4,415,700) and Brown et al (5,149,622).

Charlton et al disclose an immunoassay method for determining the presence of a ligand (analyte) in a sample. Charlton et al disclose applying a sample to an inlet of a test device which comprises a sorbent material which defines a lateral flow path, capable of transporting an aqueous solution by capillary action to a test site (detection zone). Charlton et al disclose that a conjugate comprising a protein bound to a colored particle (Reactant*) is mixed with the sample and inserted into the test device. Charlton et al also disclose that the conjugate may be predeposited in the test strip upstream of the test site (detection zone). Charlton et al disclose that the conjugate and sample flows to the test site (detection zone), which comprises latex particles entrapped or fixed in the flow path having an immobilized protein (antibody)(capturer) on their surface. Charlton et al disclose that if the analyte is present it reacts with immobilized binding

protein (antibody) at the test site and forms a sandwich comprising immobilized binding protein-ligand binding protein colored particle (Reactant*) (col 3, line 21 – col 4, line 67). Charlton et al disclose that the color particles have a size of 18 nm (0.018 um) (col 8, lines 16-18). Charlton et al disclose that that beads trapped in the test site have a size of 0.3 microns. Charlton et al also disclose packing the components into a test kit (col 4, line 17). Charlton et al disclose that the test cell can be used to detect any ligand (analyte) which has been assayed using known immunoassay procedures, or known to be detectable by such procedures (col. 4, lines 29-37).

Charlton et al differ from the instant invention in failing to teach the immobilized particles which exhibit hydrophilic groups on their surface. Charlton et al also fails to specifically teach the particles anchoring the capturer have a size, which is smaller than a smallest inner dimension of the flow channels of the matrix.

Batz et al disclose hydrophilic particles as carrier for biologically and /or immunologically active substances covalently bound to the particle (abstract). Batz et al disclose that the particles can carry substances such as, peptides, proteins, enzymes, hormones, vitamins, antigens, antibodies and micro-organisms (col 5). Batz et al disclose that the use of these hydrophilic particles provides for a diagnostic agent which has covalently bound biological and /or immunological active substances which do not impair the structure and thus the activity of the biologically active proteins (col 2, lines 59-68). Batz also disclose that these hydrophilic particles are especially useful for use in immunoassays (col 5, lines 16-19).

Brown et al disclose a flow device in which particles having a substance capable of reaction with the analyte in the sample, are immobilized in a matrix. Brown et al disclose that the average diameter of the particles is less than the average pore size of the matrix (see abstract). Brown et al disclose that by having the particle sizes having a size which is smaller than the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay, which provides for a device which is relatively easy to use and require fewer procedural steps and less complex assay technique (col 4) and is highly advantageous over devices and assay methods of the prior art.

It would have been obvious to one of ordinary skill in the art to substitute the hydrophilic particles as taught by Batz et al for the immobilized latex particles of Charlton et al because Batz et al teaches that these hydrophilic particles can be used as a solid phase in immunoassays and provides for a diagnostic agent which has covalently bound biological and /or immunological active substances which do not impair the structure and thus the activity of the biologically active proteins.

It also would have been obvious to one of ordinary skill in the art to incorporate particles which have a smaller diameter than that of the matrix as taught by Brown et al into the method of Charlton et al because Brown et al shows that by having the particle sizes having a size which is smaller than the flow channels of the matrix allows for an improved solid-phase analytical device and a binding assay which provides for a device which is relatively easy to use and require fewer procedural steps and less complex

assay technique and is highly advantageous over devices and assay methods of the prior art.

7. Claims 48, 50, 54, 55, 69, 71, 75 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al., Batz et al and Brown et al in view of Devlin et al (US 5,846,703).

See above for teachings of Charlton et al., Batz et al., and Brown et al.

Charlton et al., Batz et al, and Brown et al differ from the instant invention in failing to teach the analyte is an antibody of IgE type with specificity to allergens.

Devlin et al disclose that sandwich techniques can also be used to assay antibodies rather than antigens. Devlin et al also disclose determination of an antigen specific IgE by immobilizing antigens to solid phases. The antigens are biospecific for the corresponding antibody. Devlin et al disclose that these IgE antibodies are directed to an allergen (col 2, line 57 – col 3, line 1). Devlin et al disclose that this immunoassay allows for the measurement of antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

It would have been obvious to one of ordinary skill in the art to incorporate the use of immobilized antigens as taught by Devlin et al into the modified method of Charlton et al because Charlton et al disclose that that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or known to be detectable by such procedures and Devlin et al shows that this immunoassay allows for the detection of IgE and also allows for the measurement of antigenic substances in biological materials such as serum, plasma and whole blood and also allows for the determination of an allergen.

With respect to the flow channels having a smallest inner dimension and inner diameter and the particles anchoring the Capturer have a size in the range of 0.4-1000 um as recited in the instant claims, the optimum dimension and diameter of the flow channels and particle size can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980)

8. Claims 49, 58, 70 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al, Batz et al and Brown et al in view of Dafforn et al (US 4,981,786).

See above for teachings of Charlton et al., Batz et al., and Brown et al. Charlton et al, Batz et al and Brown et al differ from the instant invention in failing to teach the analyte is an antibody with specificity to autoantigens. Charlton et al, Batz et al and Brown et al also differ from the instant invention in failing to teach the application of reagent upstream of a sample application site.

Dafforn et al disclose the application of reagents upstream of a sample application site (col 13, lines 32-44) and also disclose detecting autoimmune antibodies (col 5, lines 1-8). Daffron et al disclose that the application of reagents in this manner and the detection of autoimmune antibodies provides for a device which is simple, rapid, accurate, and safe and avoids contamination of various reagents during their addition to the device (col 2, lines 32-42) and provides for the detection of clinically important proteins (col 4, lines61-68).

It would have been obvious to one of ordinary skill in the art to incorporate the application of reagents and the detection of autoimmune antibodies as taught by Dafforn et al into the modified method of Charlton et al because Dafforn et al shows that the application of reagents in this manner and the detection of autoimmune antibodies provides for a device which is simple, rapid, accurate, and safe and avoids contamination of various reagents during their addition to the device and provides for the detection of clinically important proteins.

9. Claims 62 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al, Batz et al and Brown et al in view of Self et al (US 4,446,231).

See above for teachings of Charlton et al, Batz et al and Brown et al. Charlton et al, Batz et al and Brown et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays have a wide application, in both clinical and non-clinical fields and that they are

particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al show that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances. Furthermore, Charlton et al disclose that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or known to be detectable by such procedures.

Response to Arguments

Applicant's argument's with respect to claims 42-83 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
July 28, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
07/31/03